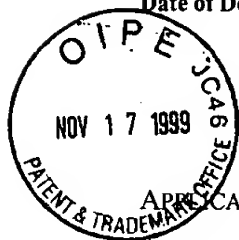


Express Mail Label No.: EJ770265675US
Date of Deposit: November 17, 1999

Attorney Docket No.: 19374-504 (GND-4)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Sean Farmer
ASSIGNEE: Ganeden Biotech, Inc.
SERIAL NUMBER: 09/369,016 EXAMINER: Not Yet Assigned
FILING DATE: August 5, 1999 ART UNIT: 1633
FOR: METHODS FOR INCREASING THE SOLUBILITY OF ESSENTIAL
VITAMINS & MINERALS IN MAMMALS USING PROBIOTIC LACTIC ACID-
PRODUCING BACTERIA, SYSTEMS, AND COMPOSITIONS

November 17, 1999
Boston, Massachusetts

BOX IDS

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed below and on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are submitted herewith. The order of presentation of the references should not be construed as an indication of the importance of the references.

U.S. Patent Documents:

<u>U.S. Patent Document No.</u>	<u>Issue Date</u>	<u>Name of Applicant(s)</u>
4,110,477	08/28/78	Naruse, <i>et al.</i>
5,079,164	01/07/92	Kirkovits, <i>et al.</i>
5,176,911	01/05/93	Tosi, <i>et al.</i>
5,439,678	08/08/95	Dobrogosz, <i>et al.</i>

Foreign Patent Documents:

<u>Patent Document No.</u>	<u>Name of Applicant(s)</u>	<u>Date of Publication</u>
WO 93/14187	Adami and Cavazzoni	July 22, 1993
WO 94/11492	Hansen's Laboratory, Inc.	May 26, 1994

Other Prior Art – Non Patent Literature Documents:

Sussman, *et al.*, 1986. Clinical manifestations and therapy of *Lactobacillus* endocarditis: report of a case and review of the literature. *Rev Infect. Dis.* 8: 771-776.

Hata, *et al.*, 1988. Meningitis caused by *Bifidobacterium* in an infant. *Pediatr. Infect. Dis.* 7: 669-671.

Reid, *et al.*, 1990. Is there a role for lactobacilli in prevention of urogenital and intestinal infections? *Clin. Microbiol. Rev.* 3: 335-344.

Gibson, *et al.*, 1995. Selective stimulation of bifidobacteria in the human colon by oligofructose and inulin. *Gastroenterology* 106: 975-982.

Saavedra, 1994. Feeding of *Bifidobacterium bifidum* and *Streptococcus thermophilus* to infants in hospital for prevention of diarrhoea and shedding of rotavirus. *Lancet* 344: 1046-109.

Mitchell, 1998. Rearming in the fight against bacteria. *Lancet* 352: 462-463.

Shannon, 1998. Multiple-antibiotic-resistant salmonella. *Lancet* 352: 490-491.

Thomason, *et al.*, 1991. Bacterial vaginosis: current review with indications for asymptomatic therapy. *Am. J. Obstet Gynecol.* 165: 1210-1217.

Marsh, 1993. Antimicrobial strategies in the prevention of dental caries. *Caries Res.* 27: 72-76.

Hill & Embil, 1986. Vaginitis: current microbiologic and clinical concepts. *Can. Med. Assoc. J.* 134: 321-331.

Fuller, R., 1989. Probiotics in man and animals. *J. Appl. Bacteriol.* 66: 365-378.

Nakamura, *et al.*, 1988. Taxonomic study for *Bacillus coagulans* Hammer 1915. *J. Systematic Bacterio.* 38: 63-73

Winberg, *et al.*, 1993. Pathogenesis of urinary tract infection-experimental studies of vaginal resistance to colonization. *Ped. Nephrol.* 7: 509-514.

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the National Application;
- ☐ within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International Application; or
- ☒ before the mailing date of a first Office Action on the merits in the above-identified case.

Accordingly, no fee or certification is required. 37 C.F.R. §1.97.

A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached modified Form PTO-1449. It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and signs the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Farmer
09/369,016

Notwithstanding any statements by the Applicant, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested. Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311 (Reference No. 19374-504; GND-4).

Respectfully submitted,



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Dated: November 17, 1999

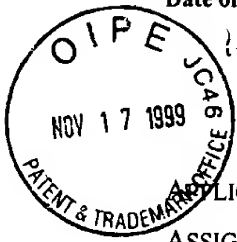
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TRANSMITTAL LETTER

Transmitted herewith for filing in the above-referenced patent application are the following documents:

- ☒ Information Disclosure Statement [4 pp.];
- ☒ Modified Form 1449/PTO, in duplicate [2 pp.];
- ☒ copies of cited references [A1-A4; B1-B2; and C1-C13]; and
- ☒ Return Postcard.

Although Applicants believe that no fees are due with this submission, the Commissioner is authorized charge any deficiencies to Deposit Account No. 50-0311 (Reference No. 19374-504; GND-4). A duplicate copy of this transmittal letter is enclosed.

If the enclosed papers are considered incomplete, the Mail Room is respectfully requested to contact the undersigned collect at (617) 542-6000, Boston, Massachusetts.

Respectfully submitted,

For R. Elrifi, Registration No. 39,529
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